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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,434	03/24/2004	Noel Coyle	PA1555 CIP1	4253

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MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
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EXAMINER

SCHELL, LAURA C

ART UNIT PAPER NUMBER

3767

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/807,434	COYLE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Laura C. Schell	3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 6-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/04-8/29/05</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Claim 2 is generic to the following disclosed patentably distinct species:

- Species A: Fig. 1
- Species B: Figs. 5 and 6
- Species C: Fig. 7
- Species D: Fig. 8
- Species E: Figs. 9-11
- Species F: Figs. 12-15

If species A is selected, one of the following subspecies of Fig. 1 must also be selected.

- Species AA: Fig. 2
- Species BB: Fig. 3a
- Species CC: Fig. 3b
- Species DD: Fig. 3c
- Species EE: Fig. 4a
- Species FF: Fig. 4b

The species are independent or distinct because each is a patentably distinct embodiment of different configurations of reinforcing members for a catheter. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this

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requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

During a telephone conversation with Ms. Catherine Maresh on 10/9/06 a provisional election was made without traverse to prosecute the invention of Species A (Fig. 1) along with subspecies DD (Fig. 3c), claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

of the following is required: There does not appear to be support in the specification for the two part reinforcing member having a stiffness that is reduced from a proximal end to a distal end, as claimed in claim 4. Figs. 1 and 3c do not any indication that this feature exists. If the examiner is mistaken, the examiner requests that page and line numbers be given where evidence of this support is found.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what exactly is slidably disposed on the shaft, as claimed in the second line from the bottom of the claim. It does not appear from the drawings that anything slides on/along the shaft, and the only thing that communicates with the guidewire lumen via the cut is the guidewire, however, if this is what the applicant is claiming, it is unclear as to how the guidewire is "slidably disposed" as the guidewire does not appear to slide along the shaft.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 2 is rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (US 2003/0105427). Lee discloses a catheter (Fig. 8) comprising: a proximal shaft (Fig. 8, the left-hand portion of 31 and Fig. 10) defining a guidewire lumen (21) and an inflation lumen (20), wherein said inflation lumen is arcuate shaped; a two part reinforcing member (22 is a reinforcing member as [0029] discloses that it can be a metal hypotube, and it has two parts, wherein the first part is the top lateral side that abuts against 32, and the second part is the arcuate bottom part that abuts 26) disposed within the inflation lumen (this is disposed within the inflation lumen, as indicated above, paragraph [0029] discloses that member 22 can be a hypotube placed within the lumen 20); and a distal shaft (Fig. 8 to the right of 31, near 27) wherein said distal shaft has a greater flexibility than said proximal shaft (as can be seen in Fig. 8, section 31 of the catheter has both reinforcing members (22 and 32), however, in the distal section, only reinforcing member (32) is present, and thus this portion has a decreased stiffness/flexibility).

In reference to claim 3, Lee discloses a transition section (the transition section in Fig. 8 begins at line 10 and ends to the left of 27, where 27 become parallel with 26 again) having a proximal end (at line 10) and a distal end (to the left of 27 where 27 becomes parallel with 26 once again), said proximal end communicating with said

proximal shaft (as defined above) and said distal end communicating with said distal shaft (as defined above).

In reference to claim 4, Lee discloses that the two part reinforcing member (22) has a stiffness that is reduced from a proximal end to a distal end (paragraph [0029 discloses how different tubes can be bonded at different regions of 22 in order to create different areas of stiffness), said two part reinforcing member extending into said transition section (Fig. 8 discloses that the two part reinforcing member (22) extends into the transition section, wherein the transition section begins at line 10 and ends to the left of 27).

In reference to claim 5, Lee discloses that the outer surface of the two part reinforcing member forms a portion of the guidewire lumen (Fig. 10 discloses that 22 abuts a portion of 32, which is located within the guidewire lumen, and hence this portion that abuts 32 is responsible for forming a portion of the guidewire lumen, just as element 42, a surrounding element, is responsible for forming another portion of the guidewire lumen, and 26 also forms a portion of the guidewire lumen at the top).

***Allowable Subject Matter***

Claim 1 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 6-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER



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